510(k) SUMMARY

ORTHO KINEMATICS, INC.

INTEGRATED SYSTEM COMPRISED OF THE KINEGRAPH VMA™ (VERTEBRAL MOTION ANALYZER) SOFTWARE AND ITS ACCESSORY DEVICE, THE MOTION NORMALIZER IMAGE™ PATIENT HANDLING AND DATA COLLECTION DEVICE (VERSION 2.0)

SUBMITTED BY	Ortho Kinematics, Inc. 7004 Bee Caves Rd., Bldg. 3, Ste. 315 Austin, Texas 78746
CONTACT PERSON	**Primary:** Adam Deitz Chief Technology Officer Ortho Kinematics Phone: (415) 699-1736 Fax: (512) 334-5500
	Alternate: Paul Gunnoe CEO Ortho Kinematics Phone: (205) 229-9328 Fax: (512) 334-5490
DATE PREPARED	July 31, 2013
510(K) NUMBER	K130743
CLASSIFICATION NAME / PRODUCT CODE	System, Image Processing, Radiological / LLZ
DEVICE CLASS	Class II
REGULATION NUMBER	21 C.F.R. 892.2050
PROPRIETARY NAME	The integral system comprised of: - the KINEGRAPH VMA™ (VERTEBRAL MOTION ANALYZER) software (version 2.0), and its accessory device, - the MOTION NORMALIZER™ patient handling and data collection device (version 2.0)

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PREDICATE DEVICE

Ortho Kinematics, Inc.'s integrated system comprised of the KINEGRAPH VMA™ (VERTEBRAL MOTION ANALYZER) software, and its accessory device, the MOTION NORMALIZER™ patient handling and data collection device (K112109) (version 1.0)

Medical Metrics, Inc.'s KIMAX QMA Radiological Image Processing System (K022585)

Steris Corporation's Steris 5085 SRT (K090136)

INTENDED USE / INDICATIONS FOR USE

The KINEGRAPH VMA™ software is a quantitative imaging software application intended to be used to process digital image files. It is designed for physicians and clinical professionals who are interested in the analysis of motion in medical images, particularly in musculoskeletal images of the spine. KINEGRAPH VMA™ software permits users to review static and dynamic digital lumbar and cervical spine images acquired with the assistance of the MOTION NORMALIZER™ patient handling and data collection device, which is designed for use by imaging technicians and intended to assist with patient lumbar and cervical bending and data collection during imaging. KINEGRAPH VMA™ software also facilitates quantitative assessment of vertebral motion in digital medical images. Information about the motion of selected objects, such as bone structures, can be generated and presented in the form of a 'motion analysis' report containing graphics, charts, and text.

TECHNOLOGICAL CHARACTERISTICS / PRINCIPLES OF OPERATION

The subject device consists of the KINEGRAPH VMA™ software that analyzes images from the MOTION NORMALIZER™ on an Off-the-Shelf ("OTS") imaging workstation. The MOTION NORMALIZER patient handling and data collection device is an accessory device to the KINEGRAPH VMA™ software that is used to assist with subject lumbar bending and data collection while images are captured with a standard fluoroscope. The MOTION NORMALIZER is comprised of two powered, electromechanical patient handling devices connected to and controlled by a console-mounted OTS computer running custom software connected to various OTS hardware accessories. The subject system is able to capture and record radiographic image data, as well as data from the patient handling devices, and to output this data into DICOM compatible digital image files for analysis using the KINEGRAPH VMA™ software.

PERFORMANCE DATA

The KINEGRAPH VMA™ software and its accessory device, the MOTION NORMALIZER™, have been designed and developed in accordance with FDA regulations, including validation and verification testing per the following FDA recognized standards:

- IEC 60601-1: Medical Electrical Equipment- Part 1: General requirements for safety (including Amendments 1 and 2) (1995).
- IEC 60601-1-2: Medical Electrical Equipment - Part 1-2: General requirements for safety - Collateral Standard: Electromagnetic Compatibility - requirements and rests (2007).

- IEC60601-1-4: Medical Electrical Equipment. Part 1: General requirements for safety. Part 1-4: Collateral Standard: Programmable electrical medical systems (2000).
- IEC60601-2-32: Medical Electrical Equipment. Part 2: Particular requirements for the safety of associated equipment of X-ray equipment (1994).
- NEMA PS 3.1 – 3.18: Digital Imaging and Communications in Medicine (DICOM) Set (2009).

In addition, the company performed a complete validation for the modified KineGraph VMA software version 2.0. Each element of the Software Requirements Specifications (SWRS) was tested and found to meet the requirements.

Finally, comparable performance and safety of the subject device to the current standard of care and/or predicate devices were verified via bench and clinical testing. Specifically:

- The accuracy and repeatability studies included in the submission of the previously-cleared version of the KineGraph VMA System (K112109) for lumbar measurements were re-run with the modified device.
- Accuracy and repeatability testing was performed for the new cervical measurements.
- Accuracy and repeatability testing on the new function to produce measurements of intervertebral translation in millimeter units was performed.

The modified KINEGRAPH VMA™ software and its accessory device, the MOTION NORMALIZER™, performed according to specifications, and equivalently to the previously-cleared device, in all bench and clinical tests.

SUBSTANTIAL EQUIVALENCE

The KINEGRAPH VMA™ software and its accessory device, the MOTION NORMALIZER™, has the same intended use and indications for use, technological characteristics, and principles of operation as the identified predicate devices. The minor technological differences between the KINEGRAPH VMA™ software and its accessory device, the MOTION NORMALIZER™, and the predicate devices raise no new issues of safety or effectiveness. Validation and verification data (including software validation) demonstrate that the subject device functions as intended, and performs functions substantially equivalent to the predicate devices.

	KineGraph VMA System v2.0 (subject device)	**KineGraph VMA System v1.1 (K112109)**	**KIMAX QMA (K022585)**	**Steris 5085 SRT (K090136)**
Classification Name	System, Image Processing, Radiological	System, Image Processing, Radiological	System, Image Processing, Radiological	Operating Room, Powered Table
Product Code	LLZ	LLZ	LLZ	FQO
Indications for	The KINEGRAPH	The KINEGRAPH	KIMAX QMA is a	The STERIS 5085

	KineGraph VMA System v2.0 (subject device)	KineGraph VMA System v1.1 (K112109)	KIMAX QMA (K022585)	Steris 5085 SRT (K090136)
Use	VMA™ software is a quantitative imaging software application intended to be used to process digital image files. It is designed for physicians and clinical professionals who are interested in the analysis of motion in medical images, particularly in musculoskeletal images of the spine. KINEGRAPH VMA™ software permits users to review static and dynamic digital lumbar and cervical spine images acquired with the assistance of the MOTION NORMALIZER™ patient handling and data collection device, which is designed for use by imaging technicians and intended to assist with patient lumbar and cervical bending and data collection during imaging. KINEGRAPH VMA™ software also facilitates quantitative assessment of vertebral motion in digital medical images. Information about the motion of selected objects, such as bone structures, can be	VMA™ software is a quantitative imaging software application intended to be used to process digital image files. It is designed for physicians and clinical professionals who are interested in the analysis of motion in medical images, particularly in musculoskeletal images of the spine. KINEGRAPH VMA™ software permits users to review static and dynamic digital lumbar spine images acquired with the assistance of the MOTION NORMALIZER™ patient handling and data collection device, which is designed for use by imaging technicians and intended to assist with patient lumbar bending and data collection during imaging. KINEGRAPH VMA™ software also facilitates quantitative assessment of vertebral motion in digital medical images. Information about the motion of selected objects, such as bone structures, can be generated and presented in the form of a 'motion analysis' report containing graphics, charts, and text.	quantitative imaging software application. It is designed for physicians and clinical professionals who are interested in the analysis of motion in medical images, particularly in musculoskeletal images. KIMAX QMA permits users to review static and dynamic digital images acquired from a variety of radiographic sources. It also facilitates quantitative assessment of motion in radiographic images. Information about the motion of selected objects, such as bone structures, can be generated and presented in the form of a 'motion analysis' report containing graphics, charts, texts.	SRT is a general surgical table with high patient weight capacity, extended width capability, and lower minimal table top elevation. The STERIS 5085 SRT accommodates all general surgical procedures including but not limited to, cardiac and vascular, endoscopic, gynecology, urology, nephrectomy, neurology, ophthalmologic, orthopedics and other procedures requiring intraoperative fluoroscopic C-arm imaging and also supports laparoscopic surgical technique for the largest surgical patients. The STERIS 5085 SRT enables patient transport on hard level surfaces within the surgical suite (from pre-operative areas to the operating room and again from the operating room to post operative recovery).

	KineGraph VMA System v2.0 (subject device)	KineGraph VMA System v1.1 (K112109)	KIMAX QMA (K022585)	Steris 5085 SRT (K090136)
	generated and presented in the form of a 'motion analysis' report containing graphics, charts, and text.			
Technological Characteristics / Functionality	• Lumbar, cervical intervertebral motion measurements • Lumbar, cervical device assisted bending	• Lumbar intervertebral motion measurements • Lumbar device assisted bending	• Cervical inter-vertebral motion measurements • Calibration of images to create measurements of intervertebral translation in millimeter units	• Cervical device assisted bending
Principles of Operation		• Same measurements with similar level of measurement accuracy and repeatability • Assists patients through a similar range of lumbar bending	• Same measurements with similar level of measurement accuracy and repeatability	• Assists patients through a similar range of cervical bending

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 6, 2013

ORTHO KINEMATICS, INC.
C/O JOHN J SMITH
PARTNER
555 13TH STREET NW
WASHINGTON DC 20005-3096

Re: K130743
Trade/Device Name: Kinegraph VMA (Vertebral Motion Analyzer) Software Version 2.0; Motion Normalizer Patient Handling and Data Collection Version 2.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 08, 2013
Received: July 08, 2013

Dear Dr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

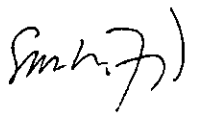
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130743

Device Name: **KINEGRAPH VMA™ (VERTEBRAL MOTION ANALYZER) software and its accessory, the MOTION NORMALIZER™ patient handling and data collection device (version 2.0)**

Indications for Use:

The KINEGRAPH VMA™ software is a quantitative imaging software application intended to be used to process digital image files. It is designed for physicians and clinical professionals who are interested in the analysis of motion in medical images, particularly in musculoskeletal images of the spine. KINEGRAPH VMA™ software permits users to review static and dynamic digital lumbar and cervical spine images acquired with the assistance of the MOTION NORMALIZER™ patient handling and data collection device, which is designed for use by imaging technicians and intended to assist with patient lumbar and cervical bending and data collection during imaging. KINEGRAPH VMA™ software also facilitates quantitative assessment of vertebral motion in digital medical images. Information about the motion of selected objects, such as bone structures, can be generated and presented in the form of a 'motion analysis' report containing graphics, charts, and text.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)